K090542

SUN-RAIN

OCT 23 2009

5. 510(K) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS
for SUN-RAIN Ultrasonic Therapy

DATE OF SUBMISSION:	February 23, 2009
SUBMITTER:	SUN-RAIN System Corp. 8F, No.125, Lane 235, Paochiao Road, Sindian City, Taiwan, ROC, 23145 TEL: 886-2-89191180 FAX:886-2-89191190
ESTABLISHMENT REGISTRATION NO:	9616346
OFFICIAL CONTACT:	Dr. JEN, KE-MIN No. 58, Fu-Chiun Street. Hsin-Chu City, TAIWAN, ROC, 30067 TEL: 886-3-5208829 FAX:886-3-5209783
TRADE NAME:	SUN-RAIN Ultrasonic Therapy, SU-300, SU-400, SU-500, SU-600, SU-700, SU-800, SU-900
COMMON/USUAL NAME:	Ultrasonic Therapy
CLASSIFICATION CODE:	IMI, Class II
REGULATION NUMBER:	890.5300
PREDICATED DEVICE:	SUN-RAIN Ultrasonic Therapy, SU-100 K024013
INTENDED USE:	The SUN-RAIN Ultrasonic Therapy generates deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

Description of Device:	Ultrasonic equipment generates high frequency sound waves that are transferred to a specific body area via a round-headed probe. The sound waves travel deep into tissue and create gentle heat. As the probe glides over the skin's surface, sound waves penetrate the skin's surface causing soft tissues to creating deep heat. In turn, the heat induces vasodilatation: drawing blood into the target tissues. The generated deep heat is found to help relieve pain and reduce muscle spasms.
Non-Clinical Tests Submitted:	The Ultrasonic Therapy equipment has been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and the particular requirements for safety of ultrasonic physiotherapy equipment. The relevant standards including: 1. IEC/EN 60601-1 : Medical electrical equipment Part 1. General requirements for safety, 1996. 2. IEC/EN 60601-1-2 : Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, 2004. 3. IEC 60601-2-5 : Safety particular requirements for ultrasonic physiotherapy equipment, 2005.
Clinical Tests Submitted:	None
Performance Tests Submitted:	1. IEC 61689 : Ultrasonics Physiotherapy systems – Field specifications and methods of measurement in the frequency range. 2. Reliability Test report.
Conclusion:	The subject new devices and the predicate device have the same indications for use and same power input. The major difference is new device of SU-400/SU-600/SU-800 is with 3MHz of frequency. Besides, the size and the dimension for the subject new devices are different. This is due to the different design and choice for the clients. Although the appearance and probe size are different but we use the same PCB and the specification is almost the same. This is not related to the safety or effectiveness. Thus the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 23 2009

SUN-RAIN System Corporation
% ROC Chinese-European Industrial Research Society
Dr. Ke-Min Jen
No. 58, Fu Chiun Street
Hsin Chu City,
Taiwan, ROC 30067

Re: K090542
Trade/Device Name: SUN-RAIN Ultrasonic Therapy, SU-300, SU-400, SU-500, SU-600, SU-700, SU-800, SU-900
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: II
Product Code: IMI
Dated: September 30, 2009
Received: October 6, 2009

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K

Device Name: SUN-RAIN Ultrasonic Therapy, SU-300, SU-400, SU-500, SU-600, SU-700, SU-800, SU-900

Indications for Use :

The SUN-RAIN Ultrasonic Therapy generates deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090542